

**REMARKS**

By this amendment, Applicants amend claims 358, 362, 364, 365, 368, 369-372, 375-378, and 382-385, and cancel claims 366 and 379. Claims 1-357 have previously been canceled. Accordingly claims 358-365, 367-378, and 380-385 remain pending and ready for examination.

**35 U.S.C. §112 Rejection**

The Office rejected claims 358-385 under 35 U.S.C. §112 as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants amend herein claims 358, 362, 364, 365, 368, 369-372, 375-378, and 382-385 and respectfully request withdrawal of the §112 rejection. The amended claims address the Examiner's concerns and meet the statutory requirements of §112.

The Office requested that Applicants specifically point out the support for the claims in the original specification. The claimed elements of the stainer are disclosed, e.g. in Fig. 6, and accompanying text at page 31-32. The claimed steps of sending commands and/or queries over the network are inherently disclosed throughout, as a person of ordinary skill in the art would recognize that the sending of commands and queries is a standard method of communication over a network. The claimed elements of a network are disclosed, e.g. in Figs. 7-9 and at page 27, lines 16-32. Inserting a reagent or a sample without interrupting the dispensing of reagents on a first sample is disclosed, e.g. at page 9, lines 9-20, page 24 lines 18-35, page 28, lines 20-24. The claimed database is disclosed, e.g. at page 27 lines 3-7. Storing information about a slide or sample is disclosed, e.g. at page 21, lines 20-35. The claimed diagnostic

operations are disclosed, e.g. at page 27, lines 3-7. Electronically notifying an operator is disclosed, e.g. at page 10, line 33. Providing a temporal estimate is disclosed, e.g. at page 17, line 32. Therefore, the original specification and drawings fully support the claims as presented.

### **35 U.S.C. §103(a) Rejections**

The claims are patentable in view of Lemme '917 at least because Lemme '917 fails to disclose or suggest all of the claimed elements.

Applicants respectfully traverse the 35 U.S.C. §103(a) rejection over Lemme et al. (U.S. 2007/0086917, "Lemme '917"). The Office Action asserts that Lemme '917 discloses or suggests all of the elements of the rejected claims. Applicants respectfully disagree. Lemme '917 does not disclose or suggest all of the elements of amended claims 358 and 372, including at least "inserting a second sample into the stainer and optionally at least one reagent into the stainer during the processing of at least one other sample without interrupting the dispensing of reagents onto the first sample with the robotic head."

The Office Action, at page 7, asserts that "[t]he slides and reagent bottles [of Lemme '917] can be changed without interrupting the dispensing of materials." The Office Action, however, cites no explicit support for this proposition, and Lemme '917 does not disclose any. Specifically, Lemme '917 does not disclose or suggest that a sample may be removed or inserted without interrupting the dispensing of a reagents onto a sample. Additionally, the system of Lemme '917 does not permit such removal and insertion at least in part because all of the slides, upon which tissue samples are placed, are mounted to the same slide drawer and individually bar code indexed. Lemme

'917 discloses, at paragraph [0043], that "the drawer 34 may be slid clear of housing 30 to permit access to all of the slide platforms 50 for slide loading and removal." Thus, in the system of Lemme '917, to gain access to the slides in order to insert an additional sample, all of the slides must be removed together. When drawer 34 is slid clear of housing 30 to permit the insertion of an additional slide, dispensing of reagents cannot continue and must be interrupted because the slides would no longer be in the correct position to receive dispensed reagent.

Moreover, removing the slide drawer is the only way to access the slides. The operator would interrupt the movement of the robot arm and most likely damage the instrument if the operator attempted to access a slide from above the probe during processing. This is because the robot arm does not move sequentially from slide to slide. Following a protocol, for each slide, the arm visits a slide, returns to the reagents, and then returns to a slide. The robot will make multiple visits to each slide and return to the reagents between each visit to a slide. Therefore, there is constant and rapid movement of the robot from reagents to slides positioned throughout the Lemme device.

Specifically, Lemme '917 discloses, at paragraph [0060] that, during processing, probe arm 400 rotates to the appropriate reagent bottle 302, aspirates a measured amount of reagent , and dispenses that reagent to the slide. Lemme '917 further discloses, at paragraph [0061], that "[t]he foregoing steps are repeated until all of the slides are processed. For convenience, in the present embodiment, the dwell time at each slide station is six and two-thirds seconds," and, at paragraph [0062], that "[t]he slide index time is preferably as short as possible." Thus, every six and two-thirds

seconds during processing, the probe arm rotates from the slide to a reagent bottle and back. While this time may vary depending on the protocols, because of the nature of the process as described above, the robot is almost always in constant motion from slide to reagents. In view of the rapid movement of the probe it would therefore be impossible to access the slides from above the probe during processing.

Furthermore, Lemme '917 discloses, at paragraph [0060], that a process sequence begins as follows: "selected reagent bottles 302 [are] mounted in the reagent support 300, the slide drawer is closed and the slide and reagent bar codes are read." At no other time in the process does Lemme '917 disclose or suggest that reagent bar codes are read. Replacing a slide during processing would cause incorrect processing steps to be performed because the system does not incorporate any means of identifying a newly inserted slide. It is therefore not possible for the system of Lemme '917 to permit inserting a second sample into the stainer during the processing of at least one other sample without interrupting the dispensing of reagents onto the first sample with the robotic head.

With regard to inserting at least one reagent into the stainer during the processing of at least one other sample without interrupting the dispensing of reagents onto the first sample with the robotic head, the Office Action appears to assert that, because Lemme '917 features multiple reagent dispensers that are accessed independently from each other, they are inherently capable of being removed without interrupting the dispensing from another reagent dispenser. On the contrary, Lemme '917 does not suggest or even permit the possibility of such replacement for the following reasons.

First, similarly to the slide bar codes, Lemme '917 discloses, at paragraph [0060], that reagent bottle bar codes are read just once at the beginning of processing. At no other time in the process does Lemme '917 disclose or suggest that reagent bar codes are read. Thus, if an operator were to replace a reagent bottle during processing, the system of Lemme '917 would have no means of knowing what reagent was in the new bottle, thus creating a likelihood that an incorrect reagent would be dispensed. Such a replacement is therefore not permitted in the system of Lemme '917.

Second, as mentioned above, every six and two-thirds seconds during processing, the probe arm rotates from the slide to a reagent bottle and back. While this time may vary depending on the protocols, because of the nature of the process as described above, the robot is almost always in constant motion from slide to reagents. Additionally, the reagent bottles are secured using a complex bracket and hinge system, illustrated in Fig. 8. There is not enough time during the six and two-thirds second window to replace a reagent bottle without interfering with the moving probe arm and thus interrupting the dispensing of reagents onto a slide. Because the system of Lemme '917 is not designed to recognize a replacement bottle, and the probe arm moves too quickly to allow an operator to replace a bottle, Lemme '917 does not disclose or suggest inserting at least one reagent into the stainer into the stainer without interrupting the dispensing of reagents onto the first sample with the robotic head, as recited by claims 358 and 372.

Therefore, because Lemme '917 does not disclose or suggest all of the elements of amended claims 358 and 372, no *prima facie* case of obviousness is supported.

Claims 359-365, 367-371, 373-378, and 380-385 depend from claims 358 and 372 and are likewise not obvious in view of the cited reference.

The claims are patentable in view of Lemme '494 at least because Lemme '494 also fails to disclose or suggest all of the claimed elements.

Applicants respectfully traverse the 35 U.S.C. §103(a) rejection over Lemme et al. (U.S. 2002/0110494 A1, "Lemme '494"). The Office Action asserts that Lemme '494 discloses or suggests all of the elements of the rejected claims. Applicants respectfully disagree. Lemme '494 does not disclose or suggest all of the elements of amended claims 358 and 372, including at least "inserting a second sample into the stainer and optionally at least one reagent into the stainer during the processing of at least one other sample without interrupting the dispensing of reagents onto the first sample with the robotic head."

Lemme '494 discloses a different system than that of Lemme '917, but fails to disclose or suggest "inserting a second sample into the stainer and optionally at least one reagent into the stainer during the processing of at least one other sample without interrupting the dispensing of reagents onto the first sample with the robotic head.," for similar reasons. As an initial matter, the device of Lemme '494 operates similarly to the Lemme '917 device. According to a predefined protocol, the slide carousel and reagent carousel are in almost constant motion as each slide is rotated to different stations and the reagents are independently rotated for dispensing.

Lemme '494, therefore, does not permit inserting a second sample into the stainer during the processing of at least one other sample without interrupting the dispensing of reagents onto the first sample with the robotic head. As shown in Figs. 1

and 3, the sample bearing slides are concealed during the operation of the system of Lemme '494. Similar to Lemme '917, Lemme '494 discloses that the dispensing operation happens very rapidly: "[a]s a guideline, each step should be performed within 6 seconds in order to speed up the process of staining." Insertion of a slide without interrupting the robotic head would require an operator to reach into the device and secure a new slide on the slide support within the six second dwell time before the slide carousel moves again. Six seconds is not enough time to safely perform this operation. Additionally, paragraph [0246] of Lemme '494 discloses that slide bar codes are read prior to a processing run, and does not disclose or suggest that bar codes are read during a processing run. Exchanging slides during a processing run would result in a sample undergoing the processing steps meant for a different sample. Lemme '494 thus does not disclose or suggest inserting a second sample into the stainer without interrupting the dispensing of reagents onto the first sample with the robotic head.

The apparatus of Lemme '494 also does not permit the insertion of at least one reagent during the processing of at least one other sample without interrupting the dispensing of reagents onto the first sample with the robotic head. Lemme '494 teaches that the reagent dispensers are mounted to a carousel, e.g. at Figs 10 and 11, that rotates the reagents into position above the slides for dispensing. Similarly to Lemme '917, Lemme '494 discloses, at paragraph [0247], that bar-codes on the reagent dispensers are read prior to a processing run, and does not disclose or suggest that bar codes are read during a processing run. Exchanging a reagent dispenser during a processing run would therefore result in incorrect reagent dispensing. Also similar to Lemme '917, Lemme '494 discloses that the dispensing operation happens very rapidly:

"[a]s a guideline, each step should be performed within 6 seconds in order to speed up the process of staining." Lemme '494 at paragraph [0250]. Lemme '494 also discloses, at paragraph [0144], the use of "spring member 448 to hold the fluid dispenser 400 firmly in place." Insertion and removal of the reagent bottles requires manipulation of the spring member. The provided six second dwell time would not permit an operator enough time to manipulate the spring member, remove a fluid dispenser, and insert a new fluid dispenser while again manipulating the spring member. Lemme '494 thus does not disclose or suggest inserting at least one reagent into the stainer during the processing of at least one other sample without interrupting the dispensing of reagents onto the first sample with the robotic head.

Therefore, because Lemme '494 does not disclose or suggest all of the elements of amended claims 358 and 372, no prima facie case of obviousness is supported. Claims 359-365, 367-371, 373-378, and 380-385 depend from claims 358 and 372 and are likewise not obvious in view of the cited reference.

### **Conclusion**

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge  
any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: January 20, 2011

By: /Richard Hanna/  
Richard M. Hanna  
Reg. No. 65,031  
(202) 408-4496